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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,568	07/30/2001	Wataru Morikawa	20-48418	2810

2292 7590 10/21/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/806,568

**Applicant(s)**

MORIKAWA ET AL.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004 and 04 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendments and Arguments***

1. Claims 1-11 and 13-17 are pending.

Claims 5-10, 13 and 14, drawn to non-elected inventions are withdrawn from examination.

Claim 12 has been cancelled.

Claims 1, 2 and 11 have been amended.

Claims 15-17 have been added.

Claims 1-4, 11 and 15-17 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objection***

#### ***Claim Objections***

3. The objection of claim 12 is withdrawn in light of the cancellation of the claim.

### ***Withdrawn Rejection***

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 11 and 12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for a method of treating lung cancer in a mouse, does not reasonably provide enablement for the said method for treating all

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cancers and preventing disease conditions merely associated with vascularization is withdrawn in light of Applicants' arguments.

5. The rejection of claims 1-4 and 11 under 35 U.S.C. 112, second paragraph presented in section 8 of the First Action on the Merits (FAOM) mailed March 1, 2004, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Claim 12 has been cancelled.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1-4 and 11 under 35 U.S.C. 102(b) as being anticipated by Gately et al. (Cancer Research 56: 4887-4890, November 1, 1996/ IDS reference on sheet 1) is withdrawn in light of the declaration filed July 22, 2004, Applicants' arguments and amendments to the claims. Claim 12 has been cancelled.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

7. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

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Applicants have added new claim 17 which includes the recitation "...which is inhibited by an aspartic protease inhibitor." Applicants have not pointedly expressed by page and line number where in the specification support is for this recitation. Applicants are requested to delete the new matter or direct the Examiner's attention to where support may be found in Applicants' disclosure for the recitation.

8. Claims 2, 3 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Applicants have amended claim 2 to recite "...an aspartic enzyme having homology to a cathepsin D precursor." Applicants have removed the recitation "a high", which presented before the term "homology" in order to obviate the rejection set forth in the FAOM. Applicants have directed the Examiner's attention to page 9, lines 17-19 of the specification. In the Remarks submitted July 1, 2004 Applicants have set forth that the N-terminal amino acid sequence shares sequence homology to the human cathepsin D precursor, see page 10, paragraph 4. Applicants should amend the claim to reflect the shared homology is *sequence* homology.

#### ***Claim Rejections - 35 USC § 102***

9. Claims 1-4, 11 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,800,814 (filed April 22, 1994). U.S. Patent #5,800,814 discloses an activation peptide which has the N-terminal amino acid

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sequence, SEQ ID NO: 1, see column 7, lines 41-49; the sequence listing listed in columns 15 and 16, particularly amino acid residues 1-11. The disclosed peptide is an aspartic protease with a pH optimum close to 3, an aspartic pH, see column 1, lines 11-13; column 2, lines 41-49. Furthermore, the disclosed activation peptide was contained in a medicament, see column 7, lines 1-37.

The patent does not specifically recite the disclosed enzyme's molecular weight, its activity, which plasma proteins are produced by the disclosed enzyme and their corresponding inhibitory activity these limitations would be inherent qualities of the disclosed aspartic enzyme in light of the fact it has an identical N-terminal amino acid sequence which would inherently function as the claimed product.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: British Journal of Cancer 81(8): 1269-1273, December 1999.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

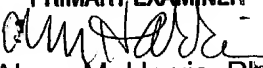
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER

  
Alana M. Harris, Ph.D.

18 October 2004